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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,954	10/09/2006	Brian David Owen Owen-Smith	133088.00701(P3716GUS)	1704

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EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,954	OWEN-SMITH, BRIAN DAVID OWEN	
	Examiner	Art Unit	
	TIFFANY M. GOUGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 7-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/08207.

Claims 7-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee (US 6753159).

Applicant claims a kit and equipment comprising reagents for determining the level of urate in a biological sample.

Both WO'207 and US 6753159 teach a method, kit and equipment comprising uricase and 3,5-dichloro-2-hydroxybenzenesulfonic acid and 4-aminophenazone for determining the level of urate in a biological sample (see WO '207 abstract, p.1,lines 20-p.2,whole page,p.3,lines 13-26,p.4, lines 10-30, p.9, lines 8-25,p.10, lines 1-7 and see US'159, abstract, col. 1,lines 10-67, col. 2, lines 25-30,56-67, col. 3,lines 1-20, col.4, lines 1-3, col.5, lines 22-30,50-59).

Thus, the references anticipate the claimed subject matter.

Claims 7-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Fossati et al. (Clin. Chem, 1980).

Applicant claims a kit and equipment comprising reagents for determining the level of urate in a biological sample.

Fossati teach a method, kit and equipment comprising uricase and 3,5-dichloro-2-hydroxybenzenesulfonic acid and 4-aminophenazone for determining the level of urate in a biological sample (see abstract, p.227 column 2, p.228, 2nd full paragraph).

Thus, the references anticipate the claimed subject matter.

Claims 7-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Owen-Smith et al. (The Lancet, 1998).

Applicant claims a kit and equipment comprising reagents for determining the level of urate in a biological sample.

Owen-Smith teach a method, kit and equipment comprising the uricase colorimetric method determining the level of urate in a biological sample, specifically saliva.

Although, the reference does not teach the specific chromogen, the uricase colorimetric method is known in the art to inherently comprise uricase and generally 4-aminoantipyrene. Therefore, the reagents of the prior art must inherently have the claimed chromogen.

Thus, the references anticipate the claimed subject matter.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Chappell et al. (Am. Journ. Obstet. Gynecol., 2002).

Applicant claims a kit and equipment comprising reagents for determining the level of urate in a biological sample.

Chappell teach a kit and equipment comprising reagents for determining the level of urate in a biological sample (p. 128, col. 2 3rd paragraph, p. 129, col.2, 1st full parag., Table II,III).

Thus, the references anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of WO 00/08207, Lee (US 6753159), and Fossati et al. (Clin. Chem, 1980) in view of Owen-Smith et al. (The Lancet, 1998) in further view of each of Dunlop et al (Brit. Med. Journal, 1978) and Schuster et al. (Gynecol. Obstet. Invest., 1981) and Pipkin (Journal of Hypertension, 2004, p.237-239).

Applicant claims a kit and equipment comprising reagents for determining the level of urate in a biological sample. Also claimed is a method for diagnosing pre-eclampsia comprising measuring urate in maternal saliva.

As stated above each of WO'207, US 6753159 and Fossati teach a method, kit and equipment comprising uricase and 3,5-dichloro-2-hydroxybenzenesulfonic acid and 4-aminophenazone for determining the level of urate in a biological sample.

The references do not teach measuring levels of urate in saliva.

Owen-Smith teach a method, kit and equipment comprising the uricase colorimetric method for determining the level of urate in a biological sample, specifically saliva.

While the above references do not teach a method for diagnosis of pre-eclampsia comprising measuring urate in maternal saliva, there is a known association between measured urate concentration levels in biological samples and pre-eclampsia. Maternal plasma urate concentrations above the normal level are generally associated with pre-eclampsia. Dunlop teaches such a correlation (see whole article) as does Schuster (see abstract) and Pipkin (see p.238, 1st and 2nd paragraphs).

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to have measured urate levels in maternal saliva in a method for diagnosing preeclampsia because the art teaches that there is a clear association between urate concentration levels and pre-eclampsia. Further, the art teaches that urate is widely distributed in extracellular fluid such as saliva. Thus, it would be obvious to one of ordinary skill in the art to use saliva as the biological fluid in the methods of WO 00/08207, Lee (US 6753159), or Fossati.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to measure urate in maternal saliva with a reasonable expectation for successfully diagnosing pre-eclampsia because the art teaches that urate is widely distributed in saliva and that there is an association between urate levels and pre-eclampsia.

Therefore, the invention as whole is prima facie obvious over the prior art.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

/Tiffany M Gough/
Examiner, Art Unit 1657